

2724-815

5/11/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

May 11, 2012

James McFadden, PhD  
Sr. Regulatory Project Manager  
Wellmark International  
1501 East Woodfield Road, Suite 200W  
Schaumburg, IL 60173

Subject: Amendment to "*add uses on puppies to the existing label*".  
RF2176 CDSO-K: EPA Reg. No. 2724-815  
Application dated December 19, 2011

Dear Dr. McFadden:

The above referenced labeling, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the following comments.

- Submit to the Agency, a revised data matrix citing associated data for MRID 47622203 (see accompanying Agency Review/DER).

Please note that we have approved the amended labeling for this product with the understanding that it is consistent with the Agency's previously stamped accepted label; and other than the revisions stated in your application (dated December 19, 2011), no other changes have been made to the labeling and/or the Confidential Statement of Formula (CSF).

See enclosed copy of the stamped label for your record. If you have any questions concerning this action please contact me or Dr. B.A. Akinlosotu via [akinlosotu.bonaventure@epa.gov](mailto:akinlosotu.bonaventure@epa.gov) or (703) 605-0653.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Suarez".

Mark Suarez,  
Product Manager (Team 13)  
Insecticide Branch  
Registration Division (7505P)

# RF2176 CDSO-K

Alternate brand name: Kirkland Signature Water-Resistant Flea & Tick Control for Dogs (Small 6-12 lbs, Medium 13-31 lbs, Large 32-79 lbs, and Extra Large 80 lbs & Over)

[Text for "Dog" in the product name must be at least 75% of the size of the largest letter in the Brand Name]

**Front panel - For Use Only on Small/Toy (6-12 lbs.), Medium (13-31 lbs.), Large (32-79 lbs.) and Extra Large (80 lbs and over) Dogs/Puppies 10 weeks of age or older**

Do not use more than one vial per dog/puppy  
**[Flea & Tick & Mosquito][Treatment] [and] Control only for Dogs/Puppies 10 weeks of age or older**  
 Effective on indoor and outdoor dogs/puppies  
 ([1][3][4][6] monthly treatments) [1][3][4][6] Months Supply [applications] [24][48] doses  
 Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]  
 [Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]  
 [Controls fleas, ticks and mosquitoes for up to one month][Monthly treatment for control of fleas, ticks and mosquitoes]  
 [Aids in Control of Ticks for up to 30 days]  
 Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [more than 10 weeks] up to [75 days][2.5 months]  
 [Starts Killing Fleas and Ticks within 15 minutes]  
 [Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]  
 [Dual Action kills adult fleas and prevents flea development]  
 [Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]  
 [Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]  
 [Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]  
 Kills the Deer Tick, which may transmit Lyme Disease  
 Kills and Repels mosquitoes (a major carrier of canine heartworm)  
 [With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]  
 Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]  
 Spreads naturally with dog's/puppy's movement (skin and hair oils)  
 [Formula][Contains lanolin for coat conditioning]  
 [Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]  
 [Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]  
 [Easy to use] Longer applicator tip for easy application to long-haired dogs/puppies  
 [Fresh][Clean][[Scent][Smell]  
 [Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar  
 [Satisfaction guaranteed or your money back]  
 Alternate Applicator claims: Unique applicator [tube] with flow control  
 [no drip][no mess][application][applicator][tube]

**ACTIVE INGREDIENTS:**

Etofenprox (CAS # 80844-07-1) .....	30.0%
S-Methoprene (CAS # 65733-16-6) .....	3.6%
Piperonyl Butoxide Technical (CAS # 51-03-6)* .....	5.0%
<b>OTHER INGREDIENTS:</b> .....	<b>61.4%</b>
<b>TOTAL</b>	<b>100.0%</b>

\*butylcarbityl (6-propylpiperonyl ether) and related compounds

**ACCEPTED**  
**With COMMENTS**  
 In EPA Letter Dated:  
 MAY 11 2012

**Under the Federal Insecticide, Fungicide  
 and Rodenticide Act, As amended, for the  
 pesticide Registered under EPA Reg. No:**

2724-815

3096

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: (Number): ..... 0.05 fl oz (1.5 cc) Applicator [tube] (Small/Toy Dogs)  
..... 0.10 fl oz (3.0 cc) Applicator [tube] (Medium Dogs)  
..... 0.20 fl oz (6.0 cc) Applicator [tube] (Large Dogs)  
..... 0.30 fl oz (9.0 cc) Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-815  
EPA Est. No.



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## RF2176 CDSO-K

**IMPORTANT! DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD.  
READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS/PUPPIES. DO NOT USE  
ON OTHER ANIMALS!  
DO NOT ALLOW CHILDREN TO APPLY PRODUCT.**

### INTRODUCTION:

[Brand] Water-Resistant Flea & Tick Control for Dogs prevents flea eggs from developing into adult fleas for up to 2.5 months. [Brand] Water-Resistant Flea & Tick Control for Dogs also controls fleas and ticks for up to 1 month and kills and repels mosquitoes for 3 to 4 weeks.

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### USE RESTRICTIONS:

RF2176 CDSO-K works by application directly to the dog's/puppy's skin, not to the hair. When applying, manually push aside dog's/puppy's hair to allow direct application to the skin. If necessary, product can be reapplied at 8 or more days after the initial application. Do not use more than one tube/vial/cartridge per dog/puppy and do not retreat more than once per month. Do not get this product in dog's/puppy's eyes or mouth. Do not allow your dog/puppy to ingest this product. (Small/toy size only - Do not apply to dogs/puppies weighing less than 6 lbs.)

[(Note: Application now assumes one applicator per dog/puppy per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

### FOR [TOY][SMALL][MEDIUM] SIZE DOGS/PUPPIES

1. Bend at perforation and tear off first applicator [tube].
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog/puppy should be standing for easy application. Apply RF2176 CDSO-K evenly to [two spots](toy/small dogs)[three spots](medium dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
4. Do not spread RF2176 CDSO-K by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12 to 24 hours after application will help to distribute the material over the skin.
5. Do not retreat more than once per month.
6. Discard empty [tube][applicator] as described in STORAGE and DISPOSAL.

[Note: Each package contains sufficient tubes/applicators for [X] applications]

### FOR [LARGE][EXTRA LARGE] DOGS

- 1 Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
- 2 Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
- 3 The dog/puppy should be standing for easy application. Apply RF2176 CDSO-K evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.

Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with RF2176 CDSO-K rapidly kills fleas and may reduce the incidence of this condition.]

[RF2176 CDSO-K is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog/puppy			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

Reminder: I purchased RF2176 CDSO-K from: \_\_\_\_\_ NOTES: \_\_\_\_\_  
Treatment table can be expanded based on package size. (6 months)

**STORAGE and DISPOSAL:** . **Pesticide Storage:** Store applicators together in a cool area away from children and animals. **Container Disposal: If empty:** Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. **If partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION**

**HAZARDS TO HUMANS:** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to Etofenprox can cause skin irritation.

**HAZARDS TO ANIMALS: DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD.** For external use only. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals. Sensitivities may occur after using ANY pesticide product for pets. Some sensitive dogs/puppies may experience temporary skin irritation such as itching or redness at the application site. If signs of sensitivity occur, bathe your dog/puppy with mild soap and rinse with large amounts of water. If signs persist or become more severe, call 1-888-987-4110 or contact your veterinarian.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.</li> <li>• Remove contact lenses, if present, after first 5 minutes, then continue rinsing</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-888-987-4110 for emergency medical treatment information.

**SIDE EFFECTS:** Monitor your dog/puppy after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or Wellmark at 1-888-987-4110



**DO NOT USE ON CATS.**  
Keep cats away from treated dogs/puppies for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

**WARRANTY AND CONDITIONS OF SALE:**

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-888-987-4110.

Wellmark International  
1501 E. Woodfield Road. 200W  
Schaumburg, Illinois 60173

[URL]

Made in USA

**TEXT FOR INDIVIDUAL APPLICATOR**

Product name  
Etofenprox 30%, S-Methoprene 3.6%, Piperonyl Butoxide 5%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**READ DIRECTIONS BEFORE USING**

EPA Reg No. 2724-815

Net Contents

[ICON – DO NOT USE ON CATS]

For Use Only on Small/Toy (6-12 lbs.), Medium (13-31 lbs.), Large (32-79 lbs.) and Extra Large (80 lbs and over) Dogs/Puppies 10 weeks of age or older

